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EXAMINER
PADGETT, MARIANNE L

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,193	Applicant(s) Dang et al
	Examiner M.L. Padgett	Group Art Unit 1762

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☐ Responsive to communication(s) filed on 4/28/03, 4/3/02 & 8/26/02.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-32 is/are pending in the application.

Of the above claim(s) 11, 16-19 & 32 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10, 12-15, 20-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 & 6

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

1. Applicant's election without traverse of Species Group A (nucleic/amino acid based) and subspecies of group ii (cell attachment factor) in Paper No. 8 is acknowledged.

Claims directed solely to non-elected species include: 11 and 16-19, and possibly 26-31.

Applicant's election with traverse of Group I, process claims 1-31 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that examination of both groups does not pose a serious burden on the examiner as they are closely related and involve overlapping searches. This is not found persuasive because product claims are only limited by method limitations in their claim language, in the structure that such techniques necessitate, hence the required areas of search for the product are much broader than the examiner is required to review for just the processes, hence adding a considerable burden.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 8-24 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Use of acronyms and abbreviations in the claims, without first defining the terms on first usage in a claim sequence is improper. In the claims, see "PTFE" in claim 6 and "P15" in claim 14. While the examiner will assume for purposes of examination that the former stands for polytetrafluoroethylene, which is commonly so abbreviated, the later term is completely unfamiliar. Review of the specification reveled repeated use that is some how associated with peptides chains, but no good definition was found, so its meaning is unclear.

It is unclear as written, when and how the limitation of claim 8, and its dependants fits in with steps (a)-(d) of the independent claim. Are they before (a) or (b) or (c) or (d)? Or are they after (d) or (c), etc...? Or could claim 8 be a further description of steps (c) or (d)? For

purposes of examination any of these situations may be considered. Please be sure to cite support for clarifying amendments.

Claims 26-31 are vague and indefinite as they further limit a limitation (step (d)), which is not positively claimed, i.e., is optional. Since step (d) is optional, there is no necessary use of any "surface-modifying group" in claim 1, consequently it is unclear if the limitations of claims 26-31 need ever be preformed. Note that in the case where an option is not chosen, non-positively claimed limitations in dependent claims of that option are also optional, and can be considered covered, when the option is not used. It is also noted, that depending on the meaning of claims 8+, i.e. if the surface modifying group or multifunctional linker is the bioactive or biocompatible agent, some of the species in these claims may be non-elected.

3. In claim 1, "at or near atmospheric a pressure" is taken to means he equivalent of --about-- or --approximately atmospheric pressure--. Also, from the context of the claims, it is considered clear, that the last two lines of claim 1, should be read as a required part of claim 1, not part of optional step (d).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-6, 8-10, 12-13, and optionally 26-31 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Beumer et al.

In Beumer et al, see the abstract; numbered paragraphs [0001-0002], [0005-0012], [0014-0022], [0025] example 1; [0029]; table 1; and claims 1-5, particularly noting teachings on use of a gas plasma to create a bonding layer (i.e. functional) using an aldehyde compound or monomer, that also serves as an activation step [0007 and 0011], where in [0012] it is taught that atmospheric pressure plasma can be used alternatively or equivalently to the common reduced pressure plasma polymer depositions, that typically use 0.1 to 1 Torr pressure. Example 1 teaches a process sequence that first employs the plasma activation step using aldehyde, then switches off the plasma power after sufficient treatment, but continues to feed monomer gas to the substrate, hence aldehyde treatment may read on an steps 1(a)-(b) or 1(a)-(b)-(c).

Beumer et al couple by covalent bonding, a cell-adhesive promoting glycoprotein having amino acid groups to the aldehyde layers, where specific types include collagens, fibronectin, vitronectin, laminin, those preferably containing lysine residues [0009, 0017-18, 0021, Ex. 2,

Table 1], and may additionally contain other biologically active molecules [0010]. These glycoproteins may read on applicant's claim 1, step (d) or elected species of the claim 8 sequence, which may or may not be the same thing.

Noteworthy teachings of substrate material include Teflon which is the trade name for polyfluorotetraethylene = PFTE or FEP, where the substrate materials are advantageously porous [0008], where enduses include cell growth materials or implantable bulk materials for uses, such as synthetic arterial surfaces, prosthetic organs like heart and lungs, immuno-assays, etc. [0022].

6. Claims 3-4, 7, 14-15 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beumer et al as applied above, optionally in view of Valentini or Clapper for claim 15.

While Beumer et al do not specify substrate shape to be tubes, the teaching of use in making synthetic arterial surfaces, and even prosthetic hearts (i.e. valves involved, etc.), would have been suggestive to one of ordinary skill in the art of tubular substrates, where the surface areas that need modification/treatment are those exposed to blood flow, i.e., the interiors of the tubes, hence making such shape obvious. The amount of aldehyde present related to its vapor pressure. hence for the taught atmospheric plasma, would have been determined by routine experimentation for the particular reactant at 1 atm or ambient pressure, as well as desired effect.

Beumer et al does not discuss "P15" nor "cadherin" molecules for attachment, however the former appears to be some sort of polypeptide sequence, which is consistent with Beumer et al's glycoproteins, and the reference taught that additional active molecules such as other proteins, glycosaminoglycans or polysaccharides, maybe used, hence other such cell adhesion

related molecules would have been obvious to employ due to this suggestion and their expected desired effects.

Alternately, the secondary references to Valentini (col. 2, lines 25-54; col. 3, lines 12-47; and col. 5, lines 17-25, cadherin as a bioactive molecule for binding protein or peptide; where collagen, fibronectin, laminin are also taught for cell attachment purposes as an alternative), or Clapper (Abstract; col. 2, lines 58-65; col. 3, line 25-col. 4, line 60; col. 8, lines 38-50+; and especially col. 9, lines 30-45+, where suitable cell adhesion molecules are given as laminin, fibronectin,... N-cadherin and P-cadherin), optionally are cited to show the obviousness of using cadherin molecules as stated above, as they are seen to be used for analogous purposes, and as alternatives to compounds taught by Beumer et al.

Ranges of densities of surface bindings are not discussed in Beumer et al, however it would have been obvious for one of ordinary skill in the art to determine desired density according to particular enduse, and compound to be coupled, via routine experimentation. Also, Beumer et al's data as shown in Tables 1-5, and discussed particularly in [0032, 0036-0039] show the ability to effect a close packed monolayer of collagen on the treated surface, which while the examiner has no means to supply numeral density values therefore, shows the ability to attach up to theoretical maximum mono-layer density, which would vary numerically depending on molecular size.

7. Claims 1-2, 5-6, 8-9 and 25 (26-31) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ikada et al (4,743,258).

8. Claims 3-4, 7 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikada et al.

Ikda et al teach treating polymeric substrates, inclusive of PTFE, porous material, and in the shape of tubes, such as may be used for vascular prostheses, via a variety of possible

techniques which include functionalizing/activating the surface by low temperature or corona discharge plasmas, where polymerized deposits may be formed simultaneous with that treatment or after by contacting the treated surface. Applicable monomers are exemplified by acrylamides, polyvinyl alcohol, vinylpyrrolidone, vinylacetate and ethylene oxide. Contact of treated and coated substrates to blood causes some degree of absorption of protein from the blood, hence reading on claimed "contacting" in claim 8. See the abstract; col. 1, lines 1-20; Summary; col. 2, line 10- col. 3, line 65, esp. col. 2, lines 64-65; and 67- col. 3, line 5. Example 2 on col. 5, provides an example using corona discharge in dry air (i.e. air with very little water, thus less than 10%, where all or any other gas therein may be considered a carrier gas), followed by immersion of treated substrate in an aqueous (H_2O containing) solutions containing polyvinylpyrrolidone, which polymerizes thereto, thus using a type of atmospheric plasma in a claim process sequence.

The teaching of Ikada et al on tube substrates differ by not giving any details of their treatment, however as it is the interiors that contact the blood, it's the interiors that would have been plasma treated, hence suggesting to one of ordinary skill in the art, that the plasma must flow through such interior spaces.

Ikada et al's Table 1 in col. 6, gives exemplary values for adsorbed proteins in $\mu g/cm^2$ amounts, however without knowing the molecular weights of these proteins, there is no way for the examiner to compare them to applicants' claimed ranges, but as the essence of the treatment is to control degree of adhesion, it would have been obvious to one of ordinary skill to adjust materials and parameter to achieve desired degree of adhesion, within the taught techniques.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-10, 12-15, 21-24 and 26-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11-16 of U.S. Patent No. 6,159,531 in view of Beumer et al (discussed above).

The independent claims of the patent differs by being directed to medical devices, and not requiring the plasma to be at atmospheric pressure, however as seen above, Beumer shows the use of both (atm plasma & medical enduses) in analogous processing, demonstrating their obviousness, especially with respect to low pressure verses atmospheric pressure, which they teach in the alternative for the plasma treating. Other dependent claims not explicitly repeated were shown to be known or obvious above.

11. Claims 1-10 and 21-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11-16 of U.S. Patent No. 6,159,531 in view of Ikada et al (discussed above).

The arguments and differences are analogous to those discussed in section 9 above, noting Ikada et al's; Examples 2 and 3 use alternative types of plasmas with the differing pressure.

12. Other art of interest includes Numura et al, who have steps and materials as claimed, except they use low pressure plasmas not atmospheric; Ishikawa et al with a rear atmospheric plasma treatment of timber, but no post-treatment; and Quincy et al who employ

corona discharge in air (similar to Ikada et al), but apply their coating before this plasma treatment, not after.

Ottembach et al cited by applicant is analogous to Ikada et al, in that they teach HF or microwave plasma or corona devices for activation of surfaces (page 11 of 20, sections 3.3 and 3.4) to enable the coating by graft polymerization in producing the Bioactive surfaces, but has no discussion of pressure. Manuyama et al (5,597,456) atmospheric plasma treats medical devices to form antithrombic or blood-compatible films, but the films are either precoated or simultaneously coated, however use plasmas of interest. The Li et al patents, propose in col. 5 to use atmospheric plasmas of noble gas or a combination of gases to chemically activate surfaces of composites and organic prior to bonding, but do not provide more specific details.

13. Any inquiry concerning this communication from the examiner should be directed to M. L. Padgett whose telephone number is (703) 308-2336. The examiner can generally be reached on Monday-Friday from about 8:30 a.m. to 4:30 p.m.; and fax phone numbers are (703) 872-9310 (regular); (703) 872-9311 (after final); and (703) 305-6078 (unofficial).

M.L. Padgett/dh 7/2/03, 7/7/03
July 8, 2003

MARIANNE PADGETT
PRIMARY EXAMINER